COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 20.8.2009
C(2009)6581

COMMISSION DECISION

of 20.8.2009

on the renewal of the marketing authorisation for the medicinal product for human use "Apidra - Insulin glulisine", granted by Decision C(2004)3653

(ONLY THE GERMAN TEXT IS AUTHENTIC)

COMMISSION DECISION

of 20.8.2009

on the renewal of the marketing authorisation for the medicinal product for human use "Apidra - Insulin glulisine", granted by Decision C(2004)3653

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1], and in particular Article 10(2) thereof,

Having regard to the application submitted by Sanofi-Aventis Deutschland GmbH, on 12 February 2009, under Article 14(2) of Regulation (EC) No 726/2004 with a view to the renewal of the marketing authorisation for the medicinal product "Apidra - Insulin glulisine"

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 29 May 2009,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[2], and in particular Article 61(3) thereof,

Whereas:

(1) On the basis of a re-evaluation by the Agency of the risk-benefit balance following the consideration of a consolidated file, it appears that the medicinal product "Apidra - Insulin glulisine", entered in the Community register of medicinal products under number(s) EU/1/04/285/001-036 and authorised by Commission Decision C(2004)3653 of 27 September 2004, complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3].

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1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 311, 28.11.2001, p. 67.
3 OJ L 311, 28.11.2001, p. 67.

(2) The marketing authorisation which expires on 29 September 2009 should therefore be renewed.

(3) Sanofi-Aventis Deutschland GmbH submitted, under Article 61(3) of Directive 2001/83/EC, a notification(s) for changes to an aspect of the labelling or the package leaflet, which has (have) not yet been included in Decision C(2004)3653 of 27 September 2004.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision C(2004)3653 of 27 September 2004 which expires on 29 September 2009 is renewed.

Article 2

Decision C(2004)3653 is amended as follows:

1) The following list of notifications for changes to an aspect of the labelling or the package leaflet is added to the updated marketing authorisation;

Application number	Annex (EU numbers affected)
EMEA/H/C/557/N/21	IIIA (EU/1/04/285/001-036)

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex II is replaced by the text set out in Annex II to this Decision;

4) Annex III is replaced by the text set out in Annex III to this Decision.

Article 3

This Decision is addressed to Sanofi-Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Deutschland.

Done at Brussels, 20.8.2009

For the Commission
Heinz ZOUREK
Director-General